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CONCEPT SELECTION IN THE DEVELOPMENT OF MEDICAL DEVICES: THE CASE OF THE SMART STENT-GRAFT

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ABSTRACT

During product development, ideas are narrowed down to a single one by the designers in order to satisfy the customers' needs. This process is called concept selection and is crucial to the development of new products because, from this point onward, the design team is committed to a concept whose modification implies delays and additional costs.

Decisions made during the concept selection phase are often difficult due to the uncertainty caused by the lack of objective data. However, it is possible to reduce this uncertainty assessing each concept's expected costs and benefits.

Medical devices, before entering the market, are scrutinized by several agencies around the world to assess their clinical- and cost-effectiveness. In order to reduce the uncertainty associated with concept selection, the parameters evaluated by the multiple agencies should be used to support the idea to pursue. However, as that data is not available yet, in this paper, several parameters are identified to evaluate each concept and, for each metric, the most adequate measurement technique is described. This paper also presents a specific implementation of the design process for a new stent-graft.

INTRODUCTION

Product development refers to the process of creating products with new or different characteristics to offer fresh or additional features to customers. While some authors describe this process with only 5 steps, others name as many as 25 stages [1]; here, the design process is divided in 8 steps, Figure 1.

Normally, the development of a product is triggered by a need or an idea. Then, the design team identifies the specific

problems that customers intend to solve purchasing a good or service (customer needs) and generate concepts. From the panoply of concepts, only one is developed and optimized. Following this, prototypes and/or small series are produced. These pre-series are evaluated by a restrict number of clients or by certifier companies. The process ends with the launch of the product in the market.

In spite of the design process being commonly represented in a linear fashion (as shown in Figure 1), the development of a product is an iterative process in which different steps can be performed simultaneously (i.e. concurrent engineering [2]).

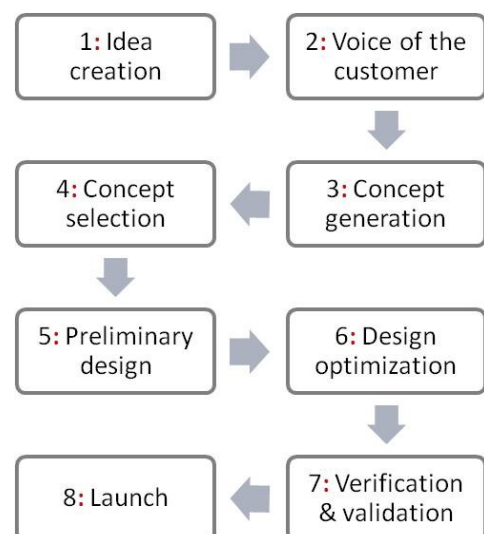


FIGURE 1: DIFFERENT STEPS OF THE PRODUCT DEVELOPMENT PROCESS

In the design process, concept selection is a vital part because from this point onward there is a convergence to a detailed solution and, according to the literature, between 60 and 80% of the cost is committed at this stage [3]. Currently, there are multiple concept selection techniques; but, they have limitations incorporating uncertainty and do not aim to quantify each concept expected cost and benefit [4].

Before entering the market, medical devices are scrutinized by different agencies around the world, namely the FDA (Food and Drug Administration) in the USA, to assess their safety, effectiveness and quality [5]. Other agencies, such as NICE (National Institute for Health and Clinical Excellence) in the UK, perform cost-effectiveness analysis and make recommendations to organizations in the public, private, voluntary and community sectors on treating specific diseases and conditions. In order to reduce the uncertainty associated with concept selection, the parameters evaluated by those agencies should be used in step 4 of Figure 1 to support the idea to pursue. However, in such an early stage of product development, data is not available. Nonetheless, other parameters can be used to estimate the concept's expected costs and benefits. In this paper, several parameters were identified to evaluate each concept for a new stent-graft and, for each metric, the most adequate measurement technique was described.

This paper is organized as follows. After an introduction to product development and concept selection, the definition of a stent-graft is presented along with the description of the disease for which it is used. Following this, multiple concepts for a stent-graft are described, and the parameters to be evaluated are identified as well as their measurement techniques. The paper then closes with the main conclusions.

AORTIC ANEURYSMS AND STENT-GRAFTS

An aortic aneurysm is a localized blood-filled dilatation of the aorta [6] that, if left untreated, may burst or rupture causing shock and even death due to massive blood loss. Among its risk factors [7], gender and age play an important role, with males over 65 years old predominantly at risk. According to the Eurostat, currently approximately 16 % of the European population is aged 65 or over. Projections estimate that this value will boom to more than 28 % in the year 2050, so consequently the disease's incidence is expected to increase as well as the demand of more cost-effective treatments.

Since the early 1950s, the common treatment of aortic aneurysms has consisted of an open surgery and the replacement of the diseased segment of the aorta by a synthetic graft. In the early 1990s, Volodos (in Ukraine) and Parodi (in Argentina) demonstrated that endovascular aneurysm repair (EVAR) was a safe and feasible procedure suitable to be an alternative to open surgery [8]. Presently, published data shows that the treatment of this condition is also viable with total laparoscopy or assisted laparoscopy [9]. Figure 2 summarizes the current management plan for aortic aneurysms. The treatment is selected considering the technology available in the medical center, the anatomy of the aneurysm, the operative risk

of repair, the patient's life expectancy, and the personal preferences of the patient.

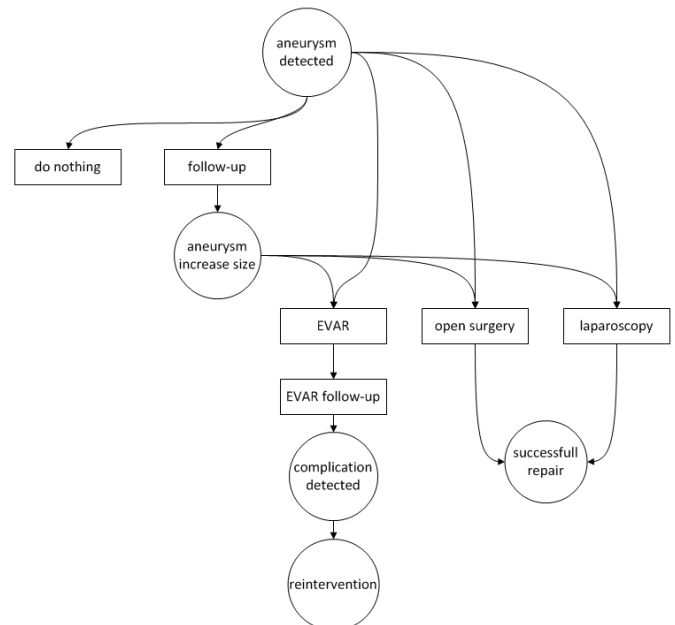


FIGURE 2: FLUXOGRAM FOR THE MANAGEMENT OF AORTIC ANEURYSMS.

EVAR (Figure 3) is a minimally invasive procedure in which an endoprosthesis - a stent-graft - is guided from the femoral artery to the affected artery segment. The objective of this procedure is to shield the aneurysm sac from the blood pressure, thus preventing the rupture of the artery wall. Although this technique is associated with advantages such as shortened hospital stays, accelerated recovery and early return to full activity, complications still occur, requiring life-long surveillance of patients [10]. Presently, surveillance protocols require imaging at 1, 6, and 12 months after the procedure, and thereafter on an annual basis [11].

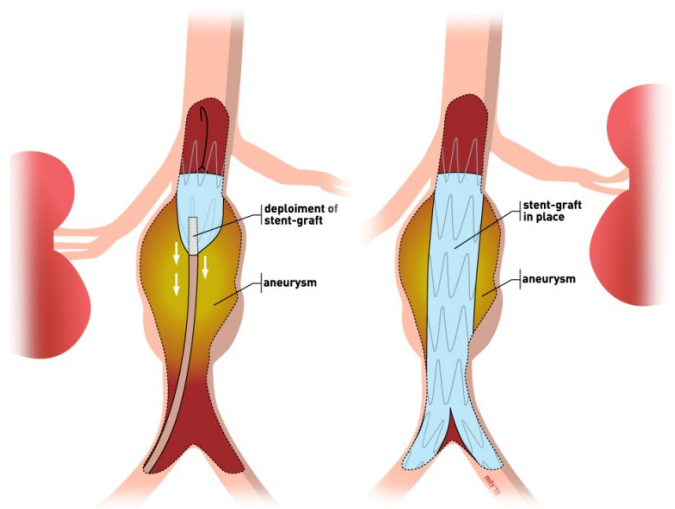


FIGURE 3: DEPLOYMENT SEQUENCE OF A STENT-GRAFT DURING EVAR.

When EVAR was introduced, it revolutionized the treatment of aortic aneurysms. However, after 20 years of use, questions are being raised regarding the follow-up costs [12] and alternative approaches are being pursued.

In order to reduce or even eliminate the need of expensive and (potentially) harmful imaging exams, the development of a smart stent-graft (a device with sensing capabilities) is being considered as an alternative. Such device would include some in-device mechanism to collect measurements regarding the device's performance and/or the patient health and can communicate with an external element. Other benefits would be the reduction of the treatment costs and the improvement of the patient's quality of life. Furthermore, it would provide information regarding the behavior of the aneurysm sac after the deployment of a stent-graft.

Although, there are patents [13,14] that propose the use of in-device smart elements to check structural integrity of grafts, drug delivery and the detection of deposits in a vessel, the technology is not commercially available. Thus, it is expected a long time before such solutions become a standard.

DEVELOPMENT OF A NEW DEVICE

The development of the smart stent-graft began with the identification of two needs: improve the performance of the existing devices and reduce EVAR's follow-up costs.

The customers' needs were gathered by reviewing the literature and conducting surveys of both patients and vascular surgeons. However, other techniques, such as interviews, could have been used [5,15].

The customers' needs and wants were then classified in accordance with the Kano Model [16], Table 1. This model classifies product requirements conform to their influence in the customers' satisfaction, Figure 4. The "must-be requirements" are basic criteria of the product; if they are not fulfilled, customers will not be interested in the product at all. With regard to the "one-dimensional requirements", customers' satisfaction is proportional to the level of fulfillment (the higher the level of fulfillment, the higher the customers' satisfaction and vice-versa); usually these requirements are explicitly demanded. The attractive requirements are neither explicitly expressed nor expected by the customers; fulfilling these requirements leads to more than proportional satisfaction, but, if they are not met, there is no feeling of dissatisfaction.

Having in consideration the ranked needs, concepts were defined as a group of features that the new device should have without referencing the technology necessary to accomplish them (Table 2). The first concept refers to a stent-graft equivalent to the current ones but with improved performance since doctors seek devices with lower profiles and a more predictable behavior. Both concepts 2 and 3 introduce smart elements; while concept 3 aims to measure flow, the second concept measures pressure. Currently, there are no devices capable of measuring blood flow, but there are two devices that measure pressure inside an aneurysm sac: the Impresure Sensor (Remon Medical, Tel Aviv, Israel) and the CardioMems EndoSure Wireless AAA Pressure Sensor (CardioMEMS, Inc,

Atlanta, USA) [11]. The fourth concept corresponds to an ideal stent-graft.

Ideally, the design team would analyze the multiple concepts and select one or combine the best features of each one creating a new concept. However, since the development and approval of a medical device is a long process, the design team should consider the possibility of open surgery or laparoscopy be improved or a new treatment for aortic aneurysm be introduced; in such case, a smart stent-graft would no longer be needed. Figure 5 shows the decisions that the design team can make.

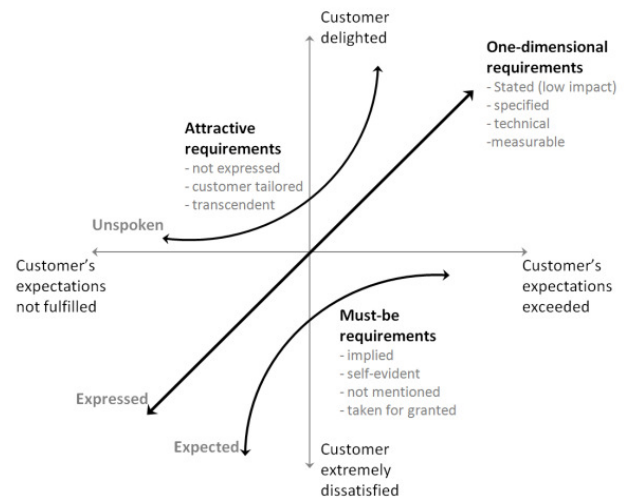


FIGURE 4: KANO'S MODEL OF CUSTOMERS' SATISFACTION.

TABLE 1: LIST OF NEEDS AND WANTS FOR THE SMART STENT-GRAFT.

Must-be	<ul style="list-style-type: none"> • Biocompatible and biostable • Non toxic, allergic and carcinogenic • Not cause thrombosis and hemolysis • Not cause inflammatory reaction or foreign body reaction • Exceed patient life expectancy • Flexible, ductile and fatigue resistant • Stable configuration • Resistant to corrosion, wear and tear • Radial force that ensures fixation and avoids leaks • Radiopaque • Sterilizable • Storable as an "off-the-shelf" product • Manufacture environmentally accepted
Satisfier	<ul style="list-style-type: none"> • Zero porosity • Predictable behavior • Wide range of diameters and lengths • Low profile
Delighter	<ul style="list-style-type: none"> • Minimizes flow resistance and pressure drops • Indicates the intraluminal pressure (systolic and diastolic) • Indicates the pressure inside the aneurysm sac at several points • Indicates if stent-graft migrates • Indicates if module disconnects • Indicates stent fractures • Indicates if graft tears • Indicates blood flow

TABLE 2: CONCEPTS FOR A SMART STENT-GRAFT.

Concept 1	Satisfies all “must-be” and “satisfier” attributes
Concept 2	Satisfies all “must-be” and “satisfier” attributes Indicates the pressure inside the aneurysm sac at several points
Concept 3	Satisfies all “must-be” and “satisfier” attributes Indicates blood flow
Concept 4	Satisfies all “must-be”, “satisfier” and “delighter” attributes

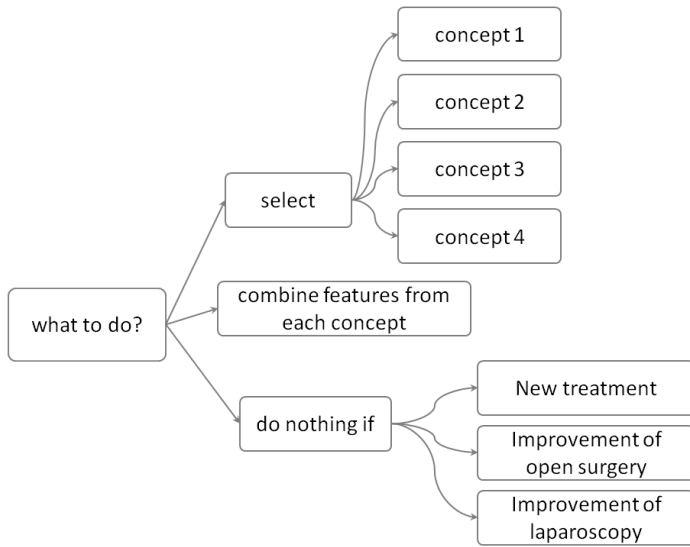


FIGURE 5: POSSIBLE DECISIONS.

The design team should select the option that provides the higher expected value (EV) defined by:

$$EV = p \cdot D \cdot \sum qm \cdot \prod ql, \quad (1)$$

in which p represents the probability of a healthy outcome using the device, D the demand, qm quantitative parameters that can be expressed in monetary units and ql qualitative parameters expressed as scaling factors.

While the demand and the probability of a healthy outcome are independent of the point of view adopted, the patient, the health professional and the one that pays may perceive the quantitative and qualitative parameters differently. In his work, Shah [17] argues that the development of medical devices benefits from the involvement of healthcare professionals and the ultimate end users. However, they are rarely the ones that decide to buy and/or pay for a device. When evaluating the concepts for a new medical device, each type of user will access the parameters differently. Thus, the expected value should be determined for each point of view and the decision should consider all of them.

The main metrics are described below as long with their measurement technique.

PROBABILITY

This parameter refers to the probability of a healthy outcome using the device, i.e. the probability of the device not causing complications or not requiring further treatments. In the case of a smart stent-graft, this value refers to the probability of

the patient being free of complications, such as endoleaks, stent-graft migration or endotension.

Using historical data is possible to calculate the probability of a healthy outcome. However, this task becomes more complicated in the case of devices yet-to-be-developed. Thus, a sensitive analysis is likely the best way to understand how the decision will be affected.

DEMAND

The demand is defined as the quantity requested by the consumers and is a function of the disease’s incidence rate and the consumers’ ability to pay. The demand of each concept can be obtained by analogy, i.e., comparing each concept with the demand of devices with similar outputs.

COST OF THE DEVICE

The cost of the device refers to the price paid to acquire the device, including its disposal. Depending on the type of the device, this value can be obtained either by analogy or by using a parametric model.

COST OF THE PROCEDURE

The cost of the procedure is the price paid for the patient to receive the device; it includes every cost from the patient’s arrival to his release from the hospital. In the case of a stent-graft, the cost of the procedure includes the imaging exams done to prepare the EVAR, the hospital stay, the operation room, the anesthesia and all the healthcare professionals involved.

This cost can be determined using a bottom-up approach (engineering buildup), which is a method that sums up all the relevant parts.

COST OF USE / MAINTENANCE

The cost of use / maintenance refers to the value spent to benefit from the device, namely medication and energy. It also includes the value spent to restore the device to a specified condition. For example, in the case of prostheses like a smart stent-graft, this parameter is the cost of the medication to avoid a foreign body reaction or the price of a reintervention to repair a complication, while the cost of use / maintenance of a computed tomography (CT) scan is the sum of the cost of energy, the space occupied and the operator.

Like the cost of the procedure, the cost of use / maintenance can be determined using a bottom-up approach.

FOLLOW-UP COST

This parameter refers to the value spent to assure the proper functioning of the device.

In the case of a stent-graft, it would include the imaging exams required by the follow-up protocol.

This parameter will be determined using a bottom-up approach.

LOSSES TO THE PATIENT

Losses to the patient reflect the value lost by the patient due to its condition; it includes the expenses that the patient and his caregiver incur due to the disease. For example, a patient that performed an EVAR has to go regularly to follow-up medical appointments; in this case, the losses refer to the work hours lost by the patient and his caregiver to attend the appointment and perform the exams that will be analyzed in

that appointment. It also includes the expenses with transportation to and from the appointment.

This parameter will be determined using a bottom-up approach.

BENEFITS TO THE COMMUNITY

A smart stent-graft avoids imaging medical exams; thus, the equipment can be used to treat and/or diagnose other conditions from others in the community. This is an example of a benefit to the community.

This parameter will be determined using a bottom-up approach.

WILLINGNESS TO PAY

Willingness to pay (WTP) means the maximum amount of medical cost a patient is willing to pay to gain benefit or prevent any risk in medical care. It may vary, depending on age, income, level of education, severity of disease, possibility of cure as well as healthcare service and culture.

WTP is expressed in monetary units. Regarding its calculation, the literature has different methods to measure the consumers' hypothetical or actual willingness to pay and whether they measure consumer willingness to pay directly or indirectly.

EFFECTIVENESS

This qualitative parameter measures the degree to which the device is successful in producing the desired result and reflects whether the device is sufficient to treat the medical condition. This parameter is equal to the number of life years gained.

MEDICATION SECURITY

Medication security reflects if the device has side effects or not. This parameter is measured in a scale, with the categories being: non-applicable (nominal), safe (benefit) and unsafe (detriment).

RISK

Risk expresses the probability or threat of a damage, injury, liability, loss, or other negative occurrence to both users and patients. It will also consider whether the device will represent a risk during its manufacture, transport and disposal. Like medication security, this parameter is measured in a scale with the categories being: neutral (nominal), very low (benefit), low, medium, high and very high (detriment).

QUALITY OF LIFE

There is an extensive literature about quality of life. In this case, quality of life will be defined as the ability to enjoy normal life activities.

RECYCLABILITY

Recyclability is a qualitative parameter that expresses the ability of the device to be captured and separated for conversion or reuse. It can be recyclable (benefit), non-recyclable (detriment) or non-applicable (neutral).

TECHNOLOGY MATURITY

The technology maturity reflects where the concept's technology known and used. This parameter is measured in a scale, with the categories being: development (detriment), introduction (neutral), growth (benefit), maturity (benefit) and decline (detriment).

FLEXIBILITY

Flexibility refers to the ability of the device to have a different application other than the one it was initially developed for, that is, to have an off-label use. It can be non-applicable, yes or no.

SCIENTIFIC BENEFIT

This parameter reflects whether the device can contribute to a better understanding of the disease in which it is used or others diseases. It can either be yes (benefit) or no (neutral).

CONCLUSIONS

In order to reduce the uncertainty associated with concept selection, multiple parameters were presented to estimate the expected value of four concepts for a new smart stent-graft. Although the problem being addressed is the development of a new endoprosthesis, the formulation adopted could be used in the selection of concepts for other medical devices, and by changing some of the quantitative and qualitative parameters, it could be used in other products.

Further research is needed to select the most appropriate way to calculate the willingness to pay and the quality of life. Furthermore, in this paper, the values of each parameter are not presented. However, the success of this concept selection technique will depend on the data gathered and used to calibrate the model.

Another issue that should be considered is the formulation of the decision problem. In the case of a device that does not pose risk to the user and has a short development time, a decision tree may be adequate. However, for prostheses, this technique may require unrealistic assumptions; in such cases, other formulations like real options theory, Bayesian networks and Markov networks should be studied.

More than 10 parameters were suggested to assess each concept and the current solutions. This may translate into a considerable effort worthwhile only for medical devices whose development time is long and requires a big investment.

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